



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/762,492

01/23/2004

Fredric R. Bloom

IVGN 347

4921

65482 7590 12/19/2008

INVITROGEN CORPORATION
C/O INTELLEVATE
P.O. BOX 52050
MINNEAPOLIS, MN 55402

EXAMINER

HINES, JANA A

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

12/19/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/762,492	Applicant(s) BLOOM ET AL.	
	Examiner JaNa Hines	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-14, 77-79 and 108-117 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-14, 77-79 and 108-117 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/24/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment Entry

1. The amendment of September 16, 2008 has been entered. Claims 1, 15-76 and 80-107 are cancelled. Claims 2-4 and 77-79 have been amended. Claims 108-117 have been newly added. Claims 2-14, 77-79 and 108-117 are under consideration in this office action.

Withdrawal of Rejections

2. The rejection of claim 78 under 35 U.S.C. 112, second paragraph, has been withdrawn in view of applicants' amendments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 2-14, 77-79 and 108-117 are rejected under 35 U.S.C. 102(b) as being anticipated by Bloom et al., (WO 00/78925 dated December 28, 2000).

Bloom et al., teach rapidly growing *E. coli* strain W that lacks endogenous plasmids, and teaches strains BRL3781, BRL3784 and *recA*- derivatives (page 3, lines 23-28). Bloom et al., teach strains wherein the modification includes alterations of the

Art Unit: 1645

recA⁻ genotype such as *recA1/recA13* or *recA* deletions, a *lacZ*⁻ genotype that allows for alpha complementation such as *lacX74 lacZΔM15* or other *lacZ* deletions a protease deficient genotype such as *Δlon* and/or *ompT*⁻, an endonuclease minus genotype such as *endA1*, a genotype suitable for M13 phage infection by including the F' episome, a restriction negative, modification positive genotype such as *hsdR17(r_K⁻, m_K⁺)*, a restriction negative, modification negative genotype such as *hsdS20(r_B⁻, m_B⁻)*, a methylase deficient genotype such as *mcrA* and/or *mcrB* and/or *mrr*, a genotype suitable for taking up large plasmids such as *deoR*, a genotype containing suppressor mutations such as *supE* and/or *supF*. Bloom et al., teach other suitable modifications are known to those skilled in the art and such modifications are considered to be within the scope of the present invention (pages 4-5, lines 22-6). Bloom et al., teach rapid growing microorganisms may be competent, chemically competent or electrocompetent (page 6, lines 3-8). Bloom et al., teach the rapid growing bacteria that have an increased growth rate that is greater than 5%, 10%, 25%, 50%, 75%, 100%, 150%, 200% than the growth rate of the reference microorganism which is *E.coli* MM294 (as known as ATCC 33625) (page 10, lines 14-19). Bloom et al., teach compositions comprising the rapidly growing microorganisms (page 17, lines 30-32). Example 3 teaches the construction of BRL3582 a *recA*⁻ *E.coli* W contained in broth.

It is noted that the instant specification at page 4, paragraphs [0008] –[0009] teach rapid growing strains such as *E. coli* strain W and BRL3781 are embodiments of the instant invention. Bloom et al., disclose the same strains (see Table 1, page 37). Page 4, [0010] states that *E.coli* strain W does not contain the genetic material of

Art Unit: 1645

bacteriophage Wphi and/or does not contain the genetic material of bacteriophage Mu and/or is resistant to infection; thus the strain W, which is the same strain disclosed by Bloom et al., do not contain any detectable levels of bacteriophage genetic material from the Wphi or Mu bacteriophage and is resistant to infection by the bacteriophages.

Thus Bloom et al., teach the claimed invention.

Response to Arguments

4. Applicant's arguments filed September 16, 2008 have been fully considered but they are not persuasive.

Applicants' argue that Bloom et al., is directed to teaching strains lacking plasmids rather than strains not containing genetic material of bacteriophage Wphi; thus lacking plasmids is not necessarily lacking bacteriophages. However, it is the position of the office The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. See MPEP § 2145 generally for case law pertinent to the consideration of applicant's rebuttal arguments.

Objective evidence which must be factually supported by an appropriate affidavit or declaration to be of probative value includes evidence of unexpected results, and

Art Unit: 1645

allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. It is noted that Applicants have not presented any experimental data showing that that as *E. coli* strain *W* or any of the strains disclosed by both Bloom et al., and the instant application having the same relevant genetic markers does not contain genetic material of bacteriophage Wphi.

Applicants argue that page 4, paragraph [0010] is in the "Summary of Invention" section and is improperly being used as in the anticipation rejection. However, the instant specification states:

"In one embodiment, the invention includes *E. coli* strain *W* that does not contain the genetic material of bacteriophage Wphi and/or does not contain the genetic material of bacteriophage Mu and/or is resistant to infection with T1."

Therefore, "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). *In re re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides.

Art Unit: 1645

The court stated that “just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel.” In this case, applicant clearly states that the *E. coli* strain W that does not contain the genetic material of bacteriophage Wphi and/or Mu and/or is resistant to infection with T1, just as required by the claims.

Furthermore, Applicants argument that because Bloom is silent with regard to the strains not contain the genetic material of bacteriophage Wphi and/or Mu, the rejection should be withdrawn is not persuasive. There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition by a person of ordinary skill in the art before the critical date and allowing expert testimony with respect to post-critical date clinical trials to show inherency); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004)(“[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention.”).

Moreover, the examiner has provided rationale tending to show inherency. The office points to page 4, paragraphs [0008] –[0009] stating that rapid growing strains such as *E. coli* strain W and BRL3781 are embodiments of the instant invention. Bloom et al., disclose the same strains (see Table 1, page 37). Both the instant specification

Art Unit: 1645

and claims 14 and 112 state that isolated E. coli strains W and C meet the limitation of being isolated E. coli strains not containing genetic material of bacteriophage Wphi or Mu. Bloom et al., teach E. coli strain W and strain C (page 14, lines 15-19). The instant specification at page 30, Table 1 and Bloom et al., at page 37, Table 1 show a list of strains used in the experiments, including the relevant genetic markers and many of the strains are the same. Thus the rationale for the inherency argument is based on the extrinsic evidence showing that the disclosed strains and the genetic markers are necessarily present in the reference, and that it would be so recognized by persons of ordinary skill. Therefore, applicants' arguments are not persuasive and the rejection is maintained.

Conclusion

5. No claims allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1645

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Robert Mondesi, can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JaNa Hines/
Examiner, Art Unit 1645

/Mark Navarro/
Primary Examiner, Art Unit 1645